

Dear national competent authorities for blood, tissues & cells and organs,

We are writing to update you on our activities relating to the Covid19 pandemic and some more general issues.

- **Covid-19 Convalescent Plasma:** A dedicated meeting of blood CAs was held on September 17th to discuss this topic. The meeting reviewed ongoing clinical trials in MS and FDA presented the rationale behind their decision to issue an Emergency Use Authorisation. In the second half of the meeting, ECDC summarised the increasingly positive scientific evidence for efficacy to date and stakeholders joined from the European Blood Alliance, Johns Hopkins University and the American Association of Blood Banks to discuss this topic, the EU CCP database and the Horizon 20:20 project SUPPORT-E. Almost 100 blood establishments have not requested to register on the EUCCP Database, developed and hosted by the Commission, and many are entering data. Over 4000 CCP donations are registered and the new module on patient transfusions is functional. Applications have been received from across the EU for funding to increase CCP collection capacity and grants will be awarded in the coming month.

- On 24 September, **ECDC published the Rapid risk assessment: Increased transmission of COVID-19 in the EU/EEA and the UK – twelfth update** <https://www.ecdc.europa.eu/en/publications-data/covid-19-risk-assessment-increased-transmission-twelfth-update>. In this update, they analyse the risk posed to the general population, vulnerable individuals, and healthcare provision by the current increase in COVID-19 case notification rates observed in the EU/EEA and the UK.

- The EDQM/Council of Europe will implement the “**Reorganisation of the Romanian Blood System**” project. The project aims to support Romania in setting up a fit-for-purpose and efficient blood transfusion system aligned with European Union and EDQM standards. The EDQM is therefore seeking experienced professionals in the field of blood transfusion to provide consultancy services. More information will be circulated to the blood authorities. For interest or information please contact purchasing@edqm.eu.

- A couple of SoHO-related meetings will take place in the **European Parliament** in the coming months – these are online meetings where stakeholders can register to attend:

o MEP Manuel Pizarro will host a round table on **Ensuring Appropriate Patient Access to PDMPs** on 14 October 2020 <https://www.eventbrite.com/e/ensuring-appropriate-patient-access-to-plasma-derived-medicinal-products-tickets-121523719717>

o The European Foundation for the Care of Newborn Infants (EFCNI, https://www.efcni.org/wp-content/uploads/2018/07/2016_09_29_Image-Broschüre_Web_kl-2.pdf) is planning a virtual workshop on the EU regulation of **human breast milk** in Parliament, moderated by MEP Mrs. Niebler, on November 18 2020. The virtual meeting will be 90 minutes long and DG Sante will make a short contribution on the BTC Evaluation. We understand that EFCNI will recommend that a revision of the European Directive on Tissues and Cells include a Delegated Act which will give the Commission the ability to develop with input from relevant stakeholders specific language on human milk. WE will inform you once registration is possible.

- PPTA will organise a Global Plasma Summit October 28-30 where our Director, Andrzej Rys will join a panel. <https://www.pptaglobal.org/meetings-events/global-plasma-summit-gps>

- Upcoming meetings:

- o **15 October** – Regular meeting of the Blood competent authorities to address standard agenda items
- o **20 October** – Informal meeting of the Organs competent authorities, organised by our colleagues in the German authority
- o **10 November** – Meeting of the Tissue and Cell competent authorities
- o **24 November** – Vigilance Expert Subgroup (to be confirmed)

Feel free to disseminate the above messages to your colleagues and establishments, as appropriate, and contact us if you wish that we share information relevant for other EU Member State SoHO Competent Authorities.

Our team continues mainly in teleworking mode and can be contacted at sante-soho@ec.europa.eu.

We hope that you and your families are keeping well.

The SoHO team,,